



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0631; FRL-9954-58]

Di-n-butyl Adipate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of di-n-butyl adipate (CAS Reg. No. 105-99-7) when used as an inert ingredient (plasticizer) at a concentration of not more than 25% by weight in pesticide formulations intended for varroa mite control around bee hives. Bayer Healthcare, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of di-n-butyl adipate.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with

the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0631, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American

Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0631 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0631, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL-9935-29), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10838) by Bayer Healthcare, LLC, Animal Health

Division, P.O Box 390 Shawnee Mission, KS 66201. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of di-n-butyl adipate, (CAS Reg. No. 105-99-7) when used as an inert ingredient (plasticizer) intended for varroa mite control around bee hives. That document referenced a summary of the petition prepared by Bayer Healthcare, LLC, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of

FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for di-n-butyl adipate

including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with di-n-butyl adipate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by di-n-butyl adipate as well as the no-observed-adverse-effect level (NOAEL) and the lowest-observed-adverse-effect level (LOAEL) from the toxicity studies are discussed in this unit.

Di-n-butyl adipate is of low acute oral toxicity, with an oral lethal dose (LD)₅₀ in rats of 1.52 gram/kilogram (g/kg) body weight. An 8-hour inhalation exposure to air saturated with di-n-butyl adipate caused no deaths in a group of 6 albino rats. Di-n-butyl adipate is not acutely toxic to rabbits by the dermal route, with a dermal LD₅₀ of 19.24 g/kg. Non-standard dermal irritation studies suggest that di-n-butyl adipate is a dermal irritant. Eye irritation studies in rabbits indicated minor eye irritation with recovery in a few days. Di-n-butyl adipate is not a dermal sensitizer in guinea pigs.

In two separate Ames Assays, no mutations were induced in any bacterial strain at any concentration of di-n-butyl adipate with or without metabolic activation. A chromosomal aberration assay was conducted on di-n-butyl adipate using cultured Chinese Hamster lung (CHL/IU) cells. Details of the study were not reported, but

structural chromosome aberrations were reported in this study with metabolic activation. In an *in vivo* micronucleus assay, no cytotoxic effects were identified in the bone marrow cells, and there was no significant increase in the number of cells with micronuclei at any dose or time after dosing.

In a reproduction and developmental toxicity study, male and female rats received di-n-butyl adipate at oral doses of 0, 100, 300 and 1,000 milligram/kilogram/day (mg/kg/day). There was no effect of di-n-butyl adipate exposure on any of the reproductive parameters measured. Pup body weight in the 1,000 mg/kg/day group was slightly reduced compared to controls at birth and on postnatal day 4. The study no-observable-adverse-effect level (NOAEL) for general toxicity in the parental generation of 300 mg/kg/day is based on the increase in kidney weights in males and females at 1,000 mg/kg/day. The NOAEL for reproduction in male and female rats was 1,000 mg/kg. The NOAEL for the F₁ generation (offspring toxicity) was 300 mg/kg/day.

The potential effects of repeated oral exposure to di-n-butyl adipate were evaluated in Sprague-Dawley rats in a 28-day toxicity test. Male and female rats received gavage doses of di-n-butyl adipate of 0, 20, 140, or 1000 mg/kg/day. No test substance-related changes were seen in any of the monitored endpoints. The NOAEL in both males and females was 1,000 mg/kg/day.

The results of the OncoLogic Quantitative Structure Activity Relationship (QSAR) model has not identified any concerns for carcinogenicity relating to di-n-butyl adipate.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

No acute toxicological endpoint of concern has been identified for di-n-butyl adipate. On the basis of the reproduction study (OECD Preliminary Reproduction Test), the NOAEL for di-n-butyl adipate was 300 mg/kg/day for offspring toxicity based on decreased in pup body weights seen at the LOAEL of 1,000 mg/kg/day was selected for risk assessment. The available toxicology data support that an Food Quality Protection Act safety factor (FQPA SF) of 3X for di-n-butyl adipate should be retained to account for uncertainties associated with subchronic to chronic extrapolation. Therefore, the

chronic population adjusted dose (cPAD) is 1 mg/kg/day based upon a NOAEL of 300 mg/kg/day and the use of 10X factors for intra- and inter- species variability and an FQPA SF of 3X.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to di-n-butyl adipate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from di-n-butyl adipate in food as follows:

Acute and chronic dietary assessments take into account exposure estimates from dietary consumption of food and drinking water. The Agency assessed the dietary exposures to di-n-butyl adipate as an inert ingredient at no more than 25% in the plastic of strips containing pesticides that are placed at the entrance to bee hives.

No adverse effects attributable to a single exposure to di-n-butyl adipate were seen in the toxicity databases; therefore, an acute dietary risk assessment is not appropriate.

In conducting the chronic dietary exposure assessment to di-n-butyl adipate the Dietary Exposure Evaluation Model/Food Commodity Intake Database (DEEM-FCID)™, Version 3.16 was used. EPA used food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for di-n-butyl adipate. In the absence of specific residue data, EPA has developed an approach that uses

surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled “Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.” (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738. Adjustments were made to the DEEM model estimates for oral exposure from the use of di-n-butyl adipate to account for the use of not more than 25% di-n-butyl adipate in strips containing pesticides that are placed at the entrance to bee hives (for honey and including exposure through drinking water) .

The Agency has not identified any concerns for carcinogenicity relating to di-n-butyl adipate; therefore, a cancer dietary exposure assessment was not performed.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for di-n-butyl adipate, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Di-n-butyl adipate may be used in inert ingredients in products that are registered for specific uses that may result in residential exposure, such as pesticides used in and around the home. Based on the available data for products registered for residential use, the Agency SOPs concluded that products containing inert chemicals similar to di-n-butyl adipate usually comprise no more than 2–5% of the inert ingredient in the final product. Therefore, the Agency conducted an assessment to represent conservative residential exposure by assessing di-n-butyl adipate in pesticide formulations (outdoor scenarios) and in disinfectant-type uses (indoor scenarios) at no more than 5% in the final formulation.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or exemption from a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found di-n-butyl adipate to share a common mechanism of toxicity with any other substances, and di-n-butyl adipate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that di-n-butyl adipate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine

which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Considering the overall toxicity profile and the endpoints and doses selected for di-n-butyl adipate, the degree of concern for the effects observed in the di-n-butyl adipate reproductive and developmental toxicity screening study is low, with a clear NOAEL for the offspring effects and regulatory doses selected to be protective of any observed effects. No other residual uncertainties were identified with respect to susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3X. That decision is based on the following findings:

- i. The toxicity database for di-n-butyl adipate is adequate to assess the safety of this chemical. However, to account for potential adverse effects from chronic exposures, an FQPA SF of 3X is retained to account for the extrapolation of adverse effects seen in subchronic toxicity studies to chronic exposure scenarios.
- ii. There is no indication that di-n-butyl adipate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.
- iii. There is some indication that potential effects of di-n-butyl adipate results in increased susceptibility in young rats in the 2-generation reproduction study but the concern is low due to the selected endpoints.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 % CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to di-n-butyl adipate in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by di-n-butyl adipate.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-,

intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, di-n-butyl adipate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to di-n-butyl adipate from food and water will utilize <1% of the cPAD for all population subgroups.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account short- and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

A short- and intermediate-term adverse effect was identified from the chronic oral end-point. Although di-n-butyl adipate is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short- or intermediate-term residential exposure, there is a possibility that di-n-butyl adipate could be used in residential pesticide products that would result in short- or intermediate-term residential exposure. As a result, the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to di-n-butyl adipate.

Using the exposure assumptions described above, EPA has concluded

that the combined chronic food and water, and short- and intermediate-term residential exposures result in aggregate MOEs of 1700 for adult males and females. Adult residential exposure combines liquids/ trigger sprayer/home garden use with a high end post application dermal exposure from contact with treated lawns. As the level of concern is for MOEs that are lower than 100, this MOE is not of concern. EPA has concluded the combined short- and intermediate-term aggregated food, water, and residential exposures result in an aggregate MOE of 3200 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). As the level of concern is for MOEs that are lower than 100, this MOE is not of concern.

4. *Aggregate cancer risk for U.S. population.* Results of a predictive Quantitative Structure Activity Relationship (QSAR) model using the OncoLogic™ Model (EPA, 2013b, version 8.0) indicate no evidence for carcinogenicity of di-n-butyl adipate. Based on the lack of evidence of carcinogenicity in the toxicity database and the model results, di-n-butyl adipate not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to di-n-butyl adipate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of di-n-butyl adipate that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption from the requirement of tolerance. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution for use on growing crops or raw agricultural commodities after harvest with concentrations of di-n-butyl adipate exceeding 25% by weight of the formulation.

B. Revisions to petitioned-for tolerances

Although not indicated the petitioner's notice of filing (NOF), the proposed concentration of di-n-butyl adipate indicated is not to exceed a maximum of 25%.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR §180.910 for di-n-butyl adipate (CAS Reg. No. 105-99-7) when used at no more than 25% by weight in pesticide formulation for varroa mite control around bee hives.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive

Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal

Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 28, 2016.

Rachel C. Holloman,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, add alphabetically the inert ingredient to the table to read as follows:

§180.910; Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
* * *	*	***
di-n-Butyl adipate (CAS Reg. No. 105-99-7)	Not to exceed 25% by weight of pesticide formulation	Plasticizer in pesticide formulations for varroa mite control around bee hives
* * *	*	***

[FR Doc. 2016-27209 Filed: 11/9/2016 8:45 am; Publication Date: 11/10/2016]